EU/New Zealand Agreement: mutual recognition in relation to conformity assessment (amendment)

2010/0139(NLE)

PURPOSE: **conclusion** of the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand.

PROPOSED ACT: Council Decision.

BACKGROUND: the Agreement between the European Community and New Zealand on mutual recognition in relation to conformity assessment entered into force on 1 January 1999. With a view to further improving and simplifying the functioning of the Agreement on Mutual Recognition, the Parties have decided to amend some of its provisions.

On the basis of the negotiating directives from the Council, the Commission initialled negotiated and initialled an Amendment to the Agreement on Mutual Recognition.

IMPACT ASSESSMENT: no impact assessment was carried out.

LEGAL BASIS: Article 207(4), first subparagraph, in conjunction with Article 218(6)(a) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the amendment is intended to:

- allow greater flexibility in the structure of Sectoral Annexes to the Agreement on Mutual Recognition,
- remove unnecessary restrictions on trade between the Parties,
- reduce the administrative burden related to management of the Agreement,
- facilitate and clarify the operation of the Agreement.

In addition, the Sectoral Annexes on medicinal products GMP (Good Manufacturing Practices) inspection and batch certification and on medical devices have been superseded by changes in technical and administrative practice and by changes in the organisations listed therein, and the opportunity has been taken to revise them.

A detailed assessment of the amendment follows.

- **scope**: in order to remove unnecessary restrictions on trade, the restriction in Article 4 of the application of the Agreement to industrial products that originate in the Parties according to non-preferential rules of origin will be deleted. As amended, the Agreement on Mutual Recognition will apply to all products covered by it, irrespective of their origin.
- **comitology**: the references to the Chair of the Joint Committee will be deleted from Articles 8 and 12, in order to reflect the fact that the Joint Committee is co-chaired by the Parties;
- **simplification of the operation of the Agreement**: in order to simplify operation of the Agreement on Mutual Recognition, a simpler procedure for the recognition, withdrawal of recognition and suspension of conformity assessment bodies will be set up in Article 12. As a result, a decision by a

designating authority to designate or withdraw designation of a conformity assessment body will no longer need to be given effect by an amendment to a Sectoral Annex; the need for the Joint Committee to take action will be limited to cases that have been contested by the other Party;

- **adaptations to the Annexes**: in order to make timely adaptations to the Sectoral Annexes to take account of technical progress and other factors such as enlargement of the European Union, Article 12 will also be amended in order to explicitly empower the Joint Committee to amend the Sectoral Annexes in areas other than to give effect to the decision by a designating authority to designate or withdraw designation of a particular conformity assessment body, and also to adopt new Sectoral Annexes;
- **sectoral Annex**: the Sectoral Annex on medicinal products and medical devices have been revised to take account of developments in technical and administrative practice, changes introduced by the Amendment to the main body of the Agreement on Mutual Recognition, updates in the organisations listed, and changes to the Parties' legislation affecting this sector. The principle of operation of this Sectoral Annex remains unchanged.

The Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Union and Australia is identical in form to the Agreement, and is therefore being amended in parallel in order to retain coherence between the Agreements.

BUDGETARY IMPLICATION: this proposal has no implications for the European Union's budget.